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December 2, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2002N-0273 – “Substances Prohibited From Use in Animal Food or Feed”

On behalf of Farm Sanctuary, the nation's largest non-profit organization dedicated to the rescue and protection of farmed animals, I wish to submit comments on the proposed rule titled “Substances Prohibited From Use in Animal Food or Feed” published in the *Federal Register* on October 6, 2005 (Vol. 70, pp. 58570-58601).

Farm Sanctuary is strongly opposed to the proposed rule. We believe the prohibition for non-ruminant feed should cover cattle organs and tissues at risk for bovine spongiform encephalopathy (BSE), including the skull, brain, spinal cord, vertebral column, neural tissue, eyes, tonsils and intestines, from cattle of all ages, as well as the complete carcasses of all dead and downed cattle. We also support prohibiting in cattle feed the use of blood, poultry litter, restaurant plate waste and all mammalian and avian protein. Our reasons for this position are described briefly below.

1. It is difficult to accurately determine the age of cattle.

The proposed rule would ban the use of brains and spinal cords only from cattle 30 months of age and older. However, determining the age of an animal at slaughter, either by written record or visual inspection, is difficult and prone to error. In January 2004, the National Joint Council of Food Inspection Locals informed the USDA that high risk materials from cattle 30 months and older were being allowed into production for human consumption. According to slaughter plant employees, the carcasses of older cattle were not always appropriately marked. A review of USDA slaughterhouse non-compliance records by the non-profit organization Public Citizen has revealed that 10 percent of the violations involved mistakes in identifying the animal's age.

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2. Infectivity with BSE is possible in younger cattle.

The proposed rule sets a 30-month threshold because infection levels are believed to rise as cattle age. However, it is known that BSE can develop in animals less than 30 months of age, and in fact cases of BSE infectivity have been found outside the U.S. in cattle younger than 30 months. Thirty months is an arbitrary criterion that does not provide citizens of the U.S. with maximum protection against transmission of BSE.

3. Visual inspection of cattle cannot detect disease.

The proposed rule would allow all materials from cattle less than 30 months of age to be used in animal feed based upon the animals being passed for human consumption by the USDA. However, the visual inspection process, where a veterinarian gives a cursory glance at hundreds of animals every hour, is completely incapable of identifying animals infected with BSE. Although the presence of severe symptoms in later stages of disease may be detected, the visual inspection process cannot be used to determine the presence or absence of a prion pathogen.

4. Infectivity is likely present in tissues other than the brain and spinal cord.

The proposed rule limits the prohibition to the brains and spinal cords from cattle passed for human consumption on the grounds that removing these materials would reduce the risk of BSE transmission by 90 percent. We argue that 90 percent is not good enough. Few people would board an airplane if they knew that there was a 10 percent chance the flight would not land safely at its destination, or drive their car if they knew there was a 10 percent chance the breaks wouldn't work. All tissues that have been shown to have a risk of infectivity should be excluded from animal feed. This would include dorsal root ganglia, trigeminal ganglia, ileum, tonsils and eyes.

5. Downed and dead cattle are at highest risk for being infected with BSE.

The proposed rule would allow materials from the carcasses of downed and dead animals, as long as the brain and spinal cord have been removed. However, it is known from European surveillance data that downed and dead cattle have a greater incidence of BSE than healthy slaughter cattle. It is not usually possible to determine by visual inspection the cause of death or the cause of an animal being non-ambulatory and, therefore, no tissues from these cattle should be allowed in feed for any animals.

6. Industry compliance with feed ban cannot be assumed.

A broader prohibition on the use of materials from cattle in animal feed must be instituted because it cannot be assumed that the meat/slaughter industry will properly segregate materials by age of the animal, type of material or whether the material originated from a healthy or sick animal. A review of slaughterhouse non-compliance records by Public Citizen showed that the USDA cited 829 violations of the BSE rules between January 2004 and

March 2005. More than half of the violations were due to a failure to even mention BSE or risk materials such as brains and spinal cords in the plant's food safety plan.

7. Inspection of industry compliance with current feed rules is inadequate.

To date, two studies conducted by the Government Accountability Office (GAO) have demonstrated inadequacies in the FDA's oversight of current animal feed rules. A study released in February 2005 found: 1) FDA has no uniform approach for identifying feed manufacturers, 2) FDA has not re-inspected about one-fifth of all feed manufacturers in five years or more, 3) FDA's feed-ban inspection guidance does not include instruction to routinely test cattle feed for prohibited materials, 4) feed intended for export is not required to carry a caution label that it may contain prohibited materials, 5) FDA has not always alerted USDA and states when it learned that cattle may have been fed prohibited materials, and 6) inspectors do not inspect cleanout procedures for vehicles used to haul cattle feed. The second GAO study, released in October, criticized FDA for being too slow in testing feed samples. According to the report, nearly half of the samples taken in 2005 required over 30 days to be processed, and some took over 100 days. By then, all the feed had probably been eaten.

The proposed rule falls far short of what the FDA promised to do two years ago upon the detection of BSE in the U.S. The only rationale provided in the preamble to the proposed rule for this reversal is cost. It is clear that FDA has watered down its proposal on animal feed to save the meat industry the costs of disposing of animal carcasses and tissues. This is a shortsighted approach given that the discovery of additional cases of BSE in the U.S. would cost the industry far more.

Thank you for the opportunity to offer our comments on this issue.

Gene Bauston

A handwritten signature in black ink, appearing to read "Gene Bauston", with a long horizontal flourish extending to the right.

President, Farm Sanctuary